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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,319	01/02/2002	Cyrus Kephra Becker	R0079C-REG	3043

24372 7590 09/05/2003  
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EXAMINER
TRUONG, TAMTHOM NGO

ART UNIT	PAPER NUMBER
1624	8

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application N .</b>	<b>Applicant(s)</b>
	10/040,319	BECKER ET AL.
	Examin r	Art Unit
	Tamthom N. Truong	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 26 June 2003 .

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 1-16, 18-24, 26, 27, 29, 30, 32, 34-38, 40, and 41 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-16, 18-24, 26, 27, 30, 32, 34-38, 40, and 41 is/are rejected.

7)  Claim(s) 29 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)      4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)      5)  Notice of Informal Patent Application (PTO-152)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s)      6)  Other: \_\_\_\_\_

### **NON-FINAL ACTION**

Applicant's amendment of 6-26-03 has been fully considered. The amended claim 1 has overcome the previous rejection of 112/2<sup>nd</sup>, and objection to the specification by amending the relationship of X and Y. Said amended claim has also overcome the lack antecedent basis of claim 10. Thus, the previous rejection and objection are withdrawn herein. However, the amended claim 1 has introduced new matter.

Claims 17, 25, 28, 31, 33, and 39 have been cancelled. Claims 40 and 42 have been added, but it is noted that there is no claim 41. Thus, claim 42 is renumbered as claim 41 according to Rule 1.126. Thus claims 1-16, 18-24, 26, 27, 29, 30, 32, 34-38, 40, and 41 are pending.

#### *Specification*

1. The amendment filed 6-26-03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

a. The limitation of N=R" does not have support in the specification as pointed out in the REMARKS.

b. The limitation of "*phenyl optionally substituted with one or two substituents selected from the group consisting of lower alkyl, halogen, cyano, and lower alkoxy.*"

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **New Matter:** Claims 1-16, 18-24, 26, 27, 30, 32, 34-38, and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1 and 40 recite the limitation of N=R'', which does not have support in the original disclosure or claims. Applicant sought support for said limitation in compounds 811 and 812 on page 70. However, said compounds do not bear such a substituent. It appears that said compounds lend support to the limitation of -N=CR'-NR'R''.

Claims 1 and 40 also recite the limitation of "*phenyl optionally substituted with one or two substituents selected from the group consisting of lower alkyl, halogen, cyano, and lower alkoxy.*" Said limitation has never been in the original disclosure.

Claims 2-16, 18-24, 26, 27, 30, 32, 34-38 are rejected as being dependent on claim 1.

2. **Lack of Enablement for "isomers...":** Claims 1-16, 18-24, 26, 27, 30, 32, 34-38, and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification

in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1 and 40 recite “individual isomers, racemic or non-racemic mixtures of isomers”. The specification does not show what the isomers are, or how they can be isolated. Furthermore, there is no guidance on which isomer would be more potent than its counterpart. Thus, for the myriad of compounds claimed herein, it would take undue experimentation for one skilled in the art to make and use “individual isomers, racemic or non-racemic mixtures of isomers.”

3. **Lack of Written Description for “isomers...”:** Claims 1-16, 18-24, 26, 27, 30, 32, 34-38, and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not identify the chiral carbons, nor does it indicate the isomer with higher potency. Thus, there is simply no written description for “individual isomers, racemic or non-racemic mixtures of isomers.”

#### *Claim Objections*

4. Claim 29 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. A search in the pertinent art area does not yield any reference teaching the species as claimed in claim 29.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (5:00-12:30) & every Saturday morning (starting from 4-7-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
T. Truong  
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September 3, 2003

  
ALAN L. ROTMAN  
SUPERVISORY PATENT EXAMINER  
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